

# HEARTS in the Americas appraisal checklist and clinical pathway for comprehensive hypertension management in primary care

Andres Rosende,<sup>1</sup> Donald DiPette,<sup>2</sup> Jeffrey Brettler,<sup>3</sup> Gonzalo Rodríguez,<sup>4</sup> Eric Zuniga,<sup>5</sup> Kenneth Connell,<sup>6</sup> Pedro Ordunez<sup>7</sup>

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## ABSTRACT

Cardiovascular diseases are the leading cause of mortality and morbidity in the Region of the Americas, and hypertension represents its main risk factor. However, population hypertension control rates in the Region are poor. Global Hearts is the World Health Organization's flagship initiative to reduce the burden of cardiovascular diseases. HEARTS in the Americas Initiative is its regional adaptation that seeks to be the cardiovascular disease risk management model, including hypertension and diabetes, in primary health care throughout the Americas by 2025.

HEARTS in the Americas is being implemented in 22 countries and over 2 095 primary care centers. All implementing countries have defined their treatment protocols, and HEARTS in the Americas has supported continuous improvement. Because WHO recently released the 2021 Guideline for the Pharmacological Treatment of Hypertension in Adults and HEARTS in the Americas introduced the key drivers for hypertension control, the initiative generated a methodology to help countries update and strengthen their treatment protocols.

This article describes the process of developing the treatment protocol appraisal checklist and defines the resulting clinical pathway. This tool can help countries and primary care centers to improve their protocols by identifying the improvement points and upgrading clinical pathways.

## Keywords

Cardiovascular diseases; hypertension; practice guideline; clinical protocols; critical pathways; public health; Americas.

Cardiovascular diseases (CVD) are the leading cause of premature mortality and morbidity in the Americas, accounting for 2 million deaths annually and a substantial negative socioeconomic impact (1). In terms of their risk factors high blood pressure is the most relevant one (2). In Latin America and the Caribbean, more than one-third of adults live with hypertension. However, even though the treatment of hypertension is

very cost-effective, relatively easy, and safe, only 23% of men and 35% of women are controlled (blood pressure < 140/90 mmHg) (3).

The Global HEARTS Initiative is a broad strategy launched in 2016 by the World Health Organization (WHO) to reduce premature CVD morbidity and mortality through the implementation of health policies at the population level and

<sup>1</sup> Pan American Health Organization, Washington, D.C., United States of America. ORCID <https://orcid.org/0000-0001-8173-0686> ✉ Andres Rosende, [rosendeand@paho.org](mailto:rosendeand@paho.org)

<sup>2</sup> University of South Carolina, Columbia, United States of America. ORCID 0000-0002-5762-9104

<sup>3</sup> Southern California Permanente Medical Group, Los Angeles, United States of America. ORCID 0000-0002-2069-9643

<sup>4</sup> Pan American Health Organization, Buenos Aires, Argentina. ORCID 0000-0001-9915-2028

<sup>5</sup> University of Antofagasta, Antofagasta, Chile. ORCID 0000-0002-1136-8260

<sup>6</sup> University of the West Indies, St. Michael, Barbados. ORCID 0000-0001-6006-2316

<sup>7</sup> Pan American Health Organization, Washington, D.C., United States of America. ORCID 0000-0002-9871-6845

strengthening CVD management in primary health care settings (4). The Pan American Health Organization (PAHO), the regional office of the WHO, initiated HEARTS in the Americas, a comprehensive CVD risk reduction program, which is poised to become the Americas' CVD care management model by 2025 (5). It is currently being implemented and expanded in 22 countries and more than 2 095 primary health care (PHC) facilities. Its fundamental goals are improved coverage and control of hypertension and CVD risk reduction in the population served.

HEARTS in the Americas is based on six technical pillars; one of the most relevant includes standardized treatment protocols and medications (5). Accordingly, the initiative created a pragmatic methodology to advance standardized and effective hypertension treatment protocols (6) based on a defined short-list of ideal antihypertensive medications (7). As a result, most HEARTS countries are progressively moving from their current (immediately implementable) protocols—based on the best available pharmacologic options for each country—to acceptable protocols emphasizing the use of two-drug combination medications in the initial management of the newly diagnosed individual with hypertension, and are taking steps to develop and implement preferred protocols, stressing the inclusion of fixed-dose combination medications in a single pill which includes molecules with ideal characteristics (8).

At the end of 2021, WHO launched the *Guideline for the Pharmacological Treatment of Hypertension in Adults* (9). In parallel, HEARTS in the Americas Innovation Group (IG) agreed on the key drivers to improve hypertension control, a set of evidence-based recommendations to make specific clinical and managerial process improvements at the PHC setting (10).

Based on these two developments (9,10) supported by extensive systematic reviews, HEARTS in the Americas developed a methodology to help countries update and strengthen their treatment protocols. As a result, an appraisal checklist was created to identify potential points of improvement in the current treatment protocols. This checklist directly led to the development of the HEARTS Clinical Pathway for Hypertension and CVD Risk Management. The clinical pathway concept comprises a multifactorial intervention for the mutual decision-making and organization of care processes for a well-defined group of patients during a well-defined period (11). The HEARTS clinical pathway meets these requirements, and its core remains a practical and effective treatment protocol.

This article aims to describe the process of developing the treatment protocol appraisal checklist and define the resulting clinical pathway. These tools can help countries and PHC centers enhance their protocols by identifying the improvement points and developing clinical pathways.

## WHO HYPERTENSION GUIDELINE AND HEARTS IN THE AMERICAS KEY DRIVERS FOR HYPERTENSION CONTROL

The new WHO hypertension guideline (9) has a remarkable implementation profile. For instance, it emphasizes a lower blood pressure threshold for initiating pharmacological treatment, increased use of CVD risk assessment in treatment decisions such as lower blood pressure treatment targets in high CVD-risk patients, the importance of using standardized and simple treatment algorithms/protocols, more substantial consideration for the use of two medications (two-pills or,

preferably, a single-pill, fixed-dose combination) in the initial treatment, and the relevance of timely patient follow-up and implementation of team-based care, among others (12).

Furthermore, based on the study of the most successful and innovative hypertension programs globally, the HEARTS in the Americas IG defined eight evidence-based hypertension control key drivers categorized into five domains:

1. Diagnosis (blood pressure measurement accuracy and CVD risk evaluation)
2. Treatment (standardized treatment protocol and treatment intensification)
3. Continuity of care and follow-up
4. Delivery system (team-based care, medication refill)
5. System for performance evaluation

Implementing the key drivers for hypertension control will allow PHC facilities to guide their program implementation, enhance their culture of quality improvement and ultimately improve hypertension control while serving as a model for other non-communicable diseases management at the PHC level in diverse settings (10).

## HEARTS IN THE AMERICAS, TREATMENT PROTOCOL APPRAISAL CHECKLIST

HEARTS in the Americas established a core advisory group of physicians and university professors from high and middle-income countries with proven clinical experience in hypertension management (internal medicine, cardiology, nephrology, and public health experts) and in-depth knowledge of the HEARTS model (5). The first goal was to design a standardized methodology to upgrade current treatment protocols by identifying specific improvement points. To this end, the advisory group defined the attributes and components of a preferred treatment protocol and then created an appraisal checklist. The preferred protocol was based on the recommendations derived from the treatment protocol model recommended by the WHO HEARTS technical package (13), the HEARTS in the Americas specific recommendations to improve treatment protocols (8), the 2021 WHO hypertension guideline (9), and the HEARTS in the Americas key drivers for hypertension control (10).

As a result, the advisory group developed a treatment protocol evaluation checklist proposal. This proposal underwent a broad consultative process involving the treatment protocol groups from each HEARTS implementing country. After several rounds of iterations, the tool was agreed upon by a broad consensus. The resulting appraisal checklist comprises 34 questions in three domains: 1) requirements to optimize protocol implementation, 2) hypertension treatment, and 3) CVD risk management. (Table 1) Each of the questions selected was accompanied by operational definitions, the evidence's certainty, recommendation type, and background source.

## HEARTS IN THE AMERICAS, A COMPREHENSIVE CLINICAL PATHWAY

A standardized, simple, directive, and algorithmic protocol represents a significant step forward in improving hypertension's clinical management (14). However, a recurring concern from HEARTS implementing countries is that HEARTS

TABLE 1. Treatment protocol appraisal checklist. HEARTS in the Americas (summary version)

Domains	Specific questions about the current treatment protocol *
<b>Requirements to optimize protocol implementation</b>	<ol style="list-style-type: none"> <li>1. Does the protocol establish a clear course of action?</li> <li>2. Does the protocol have a linear (non-branching) structure?</li> <li>3. Is the protocol PHC based?</li> <li>4. How many treatment steps are in the protocol? (Considering 4 optimal to 6 acceptable)</li> <li>5. Does the protocol include a hypertension screening strategy for all adults?</li> <li>6. Does the protocol promote a strategy that allows BP measurement by certified non-physician health workers?</li> <li>7. Does the protocol explicitly establish repeat BP measurement if the first BP reading is elevated?</li> <li>8. Does the protocol indicate an assessment of treatment adherence?</li> <li>9. Does the protocol establish a follow-up visit every 2-4 weeks until BP control is achieved?</li> <li>10. Does the protocol establish a follow-up visit every 3-6 months for low- and moderate-risk patients once the BP is under control?</li> <li>11. Does the protocol establish a follow-up visit every 3 months or less for patients with established CVD, calculated high CVD risk, diabetes, or chronic kidney disease once the BP is under control?</li> <li>12. Does the protocol promote medication titration by non-physician personnel under monitoring and by protocol?</li> <li>13. Does the protocol include the healthy lifestyle recommendations?</li> <li>14. Does the protocol fit into a strategy that ensures a 3-month supply of medications for the patient?</li> <li>15. Can the protocol be applied to manage most cases of hypertension?</li> </ol>
<b>Hypertension treatment</b>	<ol style="list-style-type: none"> <li>16. Does the protocol establish pharmacological therapy immediately after confirming a SBP <math>\geq</math> 140 mmHg or a DBP <math>\geq</math> 90 mmHg?</li> <li>17. Does the protocol intensify medication titration whenever an elevated BP is confirmed?</li> <li>18. Does the protocol establish a target &lt; 140/90 mmHg among the general adult population?</li> <li>19. Does the protocol contain only first-line medications recommended in current guidelines? (Long-acting: ACEi/ARB/CCB/TZ-TZL)</li> <li>20. Does the protocol define specific medications?</li> <li>21. Does the protocol define specific medication dosages?</li> <li>22. Does the protocol explicitly establish that medication is taken at a single daily time?</li> <li>23. Does the protocol recommend two medications combination treatment for all patients in the initial pharmacological treatment step once hypertension has been diagnosed?</li> <li>24. Does the protocol recommend fixed-dose combination antihypertensive medications?</li> <li>25. Is the antihypertensive pharmacological treatment prescribed by the protocol independent of complementary patient evaluations?</li> </ol>
<b>Cardiovascular risk management</b>	<ol style="list-style-type: none"> <li>26. Does the protocol recommend assessing CVD risk in all patients with hypertension?</li> <li>27. Is antihypertensive treatment initiated immediately regardless of CVD risk assessment?</li> <li>28. Is antihypertensive treatment initiated after confirming a SBP <math>\geq</math> 130 mmHg in patients with established CVD?</li> <li>29. Does the protocol establish a treatment target of a SBP &lt; 130 mmHg in patients with established CVD?</li> <li>30. Among patients without previous CVD, is antihypertensive treatment initiated after confirming a SBP <math>\geq</math> 130 mmHg in patients with calculated high CVD risk, diabetes or chronic kidney disease?</li> <li>31. Among patients without previous CVD, does the protocol establish a treatment target of a SBP &lt; 130 mmHg in patients with calculated high CVD risk, diabetes or chronic kidney disease?</li> <li>32. Does the protocol recommend adding high-intensity statin therapy in patients with established CVD?</li> <li>33. Among patients without previous CVD, does the protocol recommend adding moderate- to high intensity statin therapy in patients with calculated high CVD risk, diabetes or chronic kidney disease?</li> <li>34. Does the protocol recommend adding low-dose aspirin in patients with established CVD?</li> </ol>

BP: blood pressure; SBP: systolic blood pressure; DBP: diastolic blood pressure; CVD: cardiovascular diseases; PHC: primary health care; ACEi: angiotensin-converting enzyme inhibitors; ARB: angiotensin receptor blockers; CCB: calcium channel blockers; TZ-TZL: thiazide and thiazide-like diuretics.

\*Each question in the appraisal checklist has a closed option list that includes the following: Yes; No; Partially; Not available.

treatment protocol seems too top-down and is focused primarily on hypertension. Indeed, implementing countries called for a more comprehensive and inclusive clinical and management tool. In this context, the new WHO hypertension guideline and the HEARTS in the Americas key drivers for hypertension control represented timely incentives to move towards a comprehensive standardized clinical pathway.

Thus, although the clinical pathway maintained the HEARTS' standardized hypertension treatment protocol as its core, it expanded its scope to innovatively incorporate and harmonize other relevant elements to improve hypertension and the CVD secondary prevention management, the main goals of HEARTS in the Americas. (Figure 1)

The resulting standardized clinical pathway reflects “the ABCs” of CVD prevention and treatment. Indeed, it has been designed to cover most of the population, be team-driven rather than physician-centered, and actively involve patients and caregivers, all essential tenets of the chronic care model (15).

Step A advises a standardized technique for blood pressure measurement, includes a broad screening strategy, and recommends using automated and clinically validated blood pressure measuring devices for accurate blood pressure measurement (16,17). Step B encourages the healthcare team to use the HEARTS app to estimate CVD risk in all patients, but not delay the initiation of treatment if needed, and stratify them according to their CVD risk level to select the best clinical approach (18).

FIGURE 1. HEARTS in the Americas Hypertension Clinical Pathway

# Hypertension Clinical Pathway

## A ACCURATE BLOOD PRESSURE MEASUREMENT

MEASURE BLOOD PRESSURE IN ALL ADULTS AND AT ALL VISITS

- 1 Don't have a conversation
- 2 Support arm at heart level
- 3 Put the cuff on bare arm
- 4 Use correct cuff size
- 5 Support feet
- 6 Keep legs uncrossed
- 7 Empty bladder first
- 8 Support back

Whenever available, use validated automatic devices for the arm.

## B CARDIOVASCULAR RISK

KNOW YOUR RISK OF CARDIOVASCULAR DISEASE AND HOW TO MODIFY IT

### CARDIOVASCULAR RISK CALCULATOR

Use the HEARTS App to assess your cardiovascular risk

Scan code to access the cardiovascular risk calculator

This App does not replace clinical judgment.

## C TREATMENT PROTOCOL

START TREATMENT IMMEDIATELY AFTER CONFIRMING HYPERTENSION

Blood Pressure  $\geq 140/90$  mmHg in all HYPERTENSIVES.

Systolic Blood Pressure  $\geq 130$  mmHg in HIGH-RISK HYPERTENSIVES (Established cardiovascular disease, Diabetes, Chronic Kidney Disease, Risk score  $\geq 10\%$ )

Cardiovascular risk	All Hypertensives	HIGH-RISK Hypertensives	
		WITH established cardiovascular disease	WITHOUT established cardiovascular disease
Blood Pressure TARGET $<140/90$ mmHg	✓		
Systolic Blood Pressure TARGET $<130$ mmHg		✓	✓
ASPIRIN 100 mg/daily		✓	
High-dose statins: ATORVASTATIN 40 mg/daily		✓	
Moderate-dose statins: ATORVASTATIN 20 mg/daily			✓

Avoid alcohol consumption

Body mass index between 18.5 and 24.9

Avoid foods high in sodium

### 1

1 tablet of telmisartan/amlodipine 40/5 mg

1 MONTH

### 2

Patient above target after repeat measurement

1 tablet of telmisartan/amlodipine 80/10 mg

1 MONTH

### 3

Patient above target after repeat measurement

1 tablet of telmisartan/amlodipine 80/10 mg + ½ tablet of chlorthalidone 25 mg

1 MONTH

### 4

Patient above target after repeat measurement

1 tablet of telmisartan/amlodipine 80/10mg + 1 tablet of chlorthalidone 25 mg

1 MONTH

Patient above target:

Refer to the next level of care

Do 30 minutes of physical activity daily

Keep a healthy diet

No smoking

Patients under control	Minimum 6-MONTH follow-up	Minimum 3-MONTH follow-up	Supply medicines for 3 MONTHS	Vaccination		
				Influenza	Pneumococcus	COVID
All Hypertensives	✓		✓	✓		✓
HIGH-RISK Hypertensives		✓	✓	✓	✓	✓

Country Name

Entity name

ASSESS TREATMENT ADHERENCE AT EACH VISIT

TAKE ALL MEDICATIONS AT THE SAME TIME EVERY DAY

This protocol is NOT INDICATED in WOMEN of CHILDBEARING AGE

**Note:** The medications serve as examples and can be replaced with two medications from any of the three drug classes (ACEis/ARBs, CCBs or thiazide/thiazide-like diuretics). Start with a single-pill combination (fixed-dose combination) or two individual pills if fixed-dose combination is not available.



Finally, step C is the heart of the clinical pathway. This outlines a standardized treatment protocol, including pharmacological and non-pharmacological recommendations for hypertension and a comprehensive and pragmatic approach to CVD secondary prevention in PHC.

Furthermore, the HEARTS clinical pathway highlights the approach to patients with established CVD, diabetes, and chronic kidney disease. CVD risk stratification sets different blood pressure thresholds to initiate antihypertensive pharmacologic treatment, control goals, and specific recommendations for aspirin and statins. This pharmacological treatment protocol uses only four steps for medication titration at maximum, systematically repeats blood pressure measurement in each visit among patients over the target, establishes a monthly interval visit until blood pressure control is achieved, and indicates minimum follow-up intervals according to CVD risk level. Finally, it includes recommendations for COVID, influenza, and pneumococcus immunizations.

The overall goal of the clinical pathway is to enhance the quality of care, reduce the unjustified clinical performance variability, improve risk-adjusted patient outcomes, promote patient safety, increase patient participation and satisfaction, and optimize the use of resources.

## PRACTICAL IMPLICATIONS

PHC teams must support their clinical and management activities on evidence-based best practices to improve hypertension and CVD risk management. In addition, recommendations must be clear, directive, and operationalized through a standardized implementation tool to be effective. Therefore, the treatment protocol appraisal checklist and the clinical pathway adopted by HEARTS in the Americas meet all these requirements, keeping the simplicity and pragmatism necessary to facilitate its implementation.

The treatment protocol appraisal checklist allows each HEARTS implementing country to initiate a process to identify areas for improvement and then plan the changes needed to enable new treatment protocols.

Moreover, adopting a standardized clinical pathway allows the more comprehensive operationalization of the WHO hypertension guideline (9) and the implementation of HEARTS in the Americas key drivers for hypertension control in PHC (10). In addition, this clinical pathway is aligned with the HEARTS System for Monitoring Evaluation indicators, a tool designed by HEARTS in the Americas (19) to guide and catalyze health system changes.

This process is expected to lead to changes in care management organization and positively impact the selection and upgrade of medication formularies and the education and training of care teams. This work is expected to be completed by the end of 2022, resulting in more effective and practical treatment protocols and a robust and comprehensive clinical pathway.

In conclusion, the ultimate goal of the HEARTS clinical pathway is to facilitate the successful implementation of a new model of care, increase hypertension control, improve CVD risk management, and optimize the use of resources through more active and informed engagement of health teams and patients.

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## Lista de verificación para la evaluación de HEARTS en las Américas y vía clínica para el manejo integral de la hipertensión en la atención primaria de salud

### RESUMEN

Las enfermedades cardiovasculares son la principal causa de mortalidad y morbilidad en la Región de las Américas, y la hipertensión representa su principal factor de riesgo. Sin embargo, las tasas de control de la hipertensión arterial en la Región son desalentadoras. Global Hearts es la iniciativa insignia de la Organización Mundial de la Salud para reducir la carga de las enfermedades cardiovasculares. La iniciativa HEARTS en las Américas es su adaptación regional, y tiene como objetivo ser el modelo de manejo del riesgo de enfermedades cardiovasculares, incluida la hipertensión y la diabetes, en la atención primaria de salud en la Región para el año 2025.

HEARTS en las Américas se está aplicando en 22 países y más de 2 095 centros de atención primaria. Todos los países que están aplicando esta iniciativa han definido sus protocolos de tratamiento, y HEARTS en las Américas ha brindado apoyo para la mejora continua. Debido a que la OMS publicó recientemente la guía para el tratamiento farmacológico de la hipertensión en adultos (2021) y HEARTS en las Américas determinó cuáles son los impulsores clave para el control de la hipertensión, la iniciativa elaboró una metodología para ayudar a los países a actualizar y fortalecer sus protocolos de tratamiento.

En este artículo se describe el proceso de elaboración de la lista de verificación para la evaluación del protocolo de tratamiento y se define la vía clínica resultante. Esta herramienta puede ayudar a los países y los centros de atención primaria a mejorar sus protocolos para que determinen cuáles son los puntos que se deben mejorar y elaboren las vías clínicas.

### Palabras clave

Enfermedades cardiovasculares; hipertensión; guía de práctica clínica; protocolos clínicos; vías clínicas; salud pública; Américas.

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## Lista de verificação para a avaliação HEARTS nas Américas e caminho clínico para o manejo integral da hipertensão arterial na atenção primária à saúde

### RESUMO

As doenças cardiovasculares são a principal causa de morbimortalidade na Região das Américas, e a hipertensão é seu principal fator de risco. Entretanto, as taxas de controle da hipertensão na população da Região são baixas. *Global Hearts* é a principal iniciativa da Organização Mundial da Saúde para reduzir a carga de doenças cardiovasculares. A iniciativa HEARTS nas Américas é sua adaptação regional, que almeja ser o modelo para o gerenciamento de risco de doenças cardiovasculares, incluindo a hipertensão e o diabetes, na atenção primária à saúde em toda a Região das Américas até 2025.

A iniciativa HEARTS nas Américas está sendo implementada em 22 países e mais de 2 095 centros de atenção primária à saúde. Todos os países que estão implementando a iniciativa definiram seus protocolos de tratamento, e a HEARTS nas Américas contribuiu para a melhoria contínua. Como a OMS lançou recentemente as *Diretrizes de 2021 para o tratamento medicamentoso da hipertensão arterial em adultos* e a HEARTS nas Américas desenvolveu os elementos essenciais para o controle da hipertensão, a iniciativa criou uma metodologia para auxiliar os países na atualização e no fortalecimento de seus protocolos de tratamento.

Este artigo descreve o processo de elaboração da lista de verificação para avaliação do protocolo de tratamento e define o caminho clínico resultante. Esta ferramenta pode ajudar os países e os centros de atenção primária à saúde a aprimorarem seus protocolos mediante a identificação dos pontos para melhoria e o desenvolvimento de caminhos clínicos.

### Palavras-chave

Doenças cardiovasculares; hipertensão; guia de prática clínica; protocolos clínicos; procedimentos clínicos; saúde pública; América.

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